

### REMARKS

Claims 1, 2, 4, 6 and 13-17 are pending in the above-identified application. Support for new claim 16 is found at pages 3-8 of the present specification as well as in the examples described at pages 23-37 therein. Support for new claim 17 is found at page 17, lines 23-25 of the specification.

#### Interview Conducted with Patent Examiner

Applicant's representative appreciates the time taken by the Examiner to conduct a telephonic Interview on August 3, 2010. During the Interview the representative pointed out that Tanaka '339 does not employ gaseous carbon dioxide in a sealed environment together with a viscous absorption aid composition employed in the present invention. Rather Tanaka '339 relies on generation of carbon dioxide from a chemical reaction and requires bubble formation. Nishino '189 is limited to supplying carbon dioxide gas to the skin, without any mention or suggestion that a viscous absorption aid composition could additionally be employed.

The Examiner essentially maintained his position as stated in the last Office Action, though he noted that submission of "method" claims may correspond more closely to the evidence submitted into the record and relied upon from the present specification concerning improved carbon dioxide absorption. The representative also submitted that the Tanaka Declaration under 37 CFR 1.132 provided an appropriate comparison between an embodiment of the present invention (absorption aid/sealed enclosure/carbon dioxide gas) and Example 299 from the cited Tanaka '339 reference (absorption aid with chemical components that generate carbon dioxide gas with no sealed enclosure member or outside source of carbon dioxide gas). It is respectfully requested that the Examiner consider the following comments in light of the Interview.

#### Issues under 35 USC 103(a)

Claims 1, 4, 6, 13 and 14 have been rejected under 35 USC 103(a) as being unpatentable over Nishino '189 (JP 07-171189) and further in view of Tanaka '339 (WO 99/24043 corresponding to US 6,689,339).

Claim 2 has been rejected under 35 USC 103(a) as being unpatentable over Nishino '189 in view of Tanaka '339, and further in view of Westwood '340 (WO 98/173340).

Claim 15 has been rejected under 35 USC 103(a) as being unpatentable over Nishino '189 in view of Tanaka '339, and further in view of Gedouin '366 (US 6,258,366).

The above rejections are traversed based on the following reasons.

*Present Invention and Its Advantages*

The present invention is directed to a carbon dioxide external administration device which includes a sealing enclosure member containing an absorption aid together with a gas supply for supplying carbon dioxide gas into the sealing enclosure member, wherein the absorption aid is a viscous material containing sodium alginate or propylene glycol alginate, as recited in claim 1, for example. The present invention is also directed to a method for transdermal or transmucosal absorption of carbon dioxide by a human which includes applying the absorption aid onto a surface of a human, sealing the surface with an enclosure member from the outside air, and supplying carbon dioxide gas into the sealing enclosure member, as recited in new claim 16, for example. The device and method of the present invention advantageously provide for the dissolution of carbon dioxide in the absorption aid so as to allow for advantageously effective transdermal or transmucosal absorption of the carbon dioxide into the skin tissue. The effectiveness of the device and method of the present invention is supported by the numerous examples described at pages 23-37 of the present specification.

In order to further support the advantageous properties exhibited by the present invention over an example from the prior art, believed by Applicant to be the closest prior art example, Applicant submitted the Declaration of Masaya Tanaka under 37 CFR 1.132 (herein the "Tanaka Declaration"). The Tanaka Declaration compared Example 2 described at pages 25-26 of the present specification against Example 299 of Tanaka '339. As noted above and as described at the present specification, the device and method of the present invention advantageously provides for the dissolving carbon dioxide in order to enhance transdermal and/or transmucosal absorption thereof. In contrast, as discussed in more detail below, Tanaka '339 discloses aqueous viscous compositions and methods employing the same wherein the compositions contain chemical components that generate carbon dioxide bubbles so that the carbon dioxide gas from the bubbles is exposed to the skin tissue directly. This contrasts with the present invention wherein a separate source of carbon dioxide gas is supplied to a sealed portion of a human surface having the absorption aid disposed thereon. The Tanaka Declaration shows that Example

2 of the present invention exhibits advantageously higher skin temperature properties when compared to Example '299 of Tanaka '339. As noted in section (4) on pages 3-4 of the Tanaka Declaration, an increase in skin temperature correlates to an increase in skin moisture content and sebum output which is consistent with Example 1 at pages 23-25 of the present specification. The Tanaka Declaration concludes that Example 2 in accordance with the present invention and employing sodium alginate, as also used in Example 299 of Tanaka '339, exhibited advantageously improved skin temperatures which correlates to improved skin moisture content and sebum output properties. In this regard, note that the color versions of the gloved hands shown in Table 2 correspond to an advantageously strong shade of green for Subjects A and B of Example 2, as compared to a disadvantageously strong shade of blue for Subjects A and B of Example 299 of Tanaka '339. Finally, the Tanaka Declaration explains that the results shown for the use of sodium alginate are expected to correspond to results expected for replacing this component with propylene glycol alginate, a compound to having similar properties in the context of its use here.

#### Distinctions over Cited References

Tanaka '339 discloses viscous compositions which contain carbon dioxide in gaseous or "bubble" form as mentioned, for example, at column 2, lines 37-41 and column 6, lines 25-33, among other portions of the description. Tanaka '339 repeatedly makes it very clear that the carbon dioxide gas is to remain in the form of bubbles for exposure to the skin tissue. In addition, Tanaka '339 employs in the examples therein chemical components which react to form carbon dioxide, in contrast to an outside carbon dioxide source.

Tanaka '339 fails to disclose a device or method employing an absorption aid that is a viscous material containing sodium alginate or propylene glycol alginate which dissolves supplied carbon dioxide gas, such that the carbon dioxide is no longer in "bubble" form. Tanaka '339 also fails to disclose or suggest employing a sealed enclosure into which carbon dioxide gas is supplied so that the gas is advantageously effectively absorbed transdermally or transmucosally, as in the device and method of the present invention. The Tanaka Declaration discussed above clearly evidences the fact that the dissolved carbon dioxide employed in the absorption aid of the present invention exhibits advantageously improved skin temperature raising properties which ultimately correspond to improved transdermal and/or transmucosal

absorption of the carbon dioxide, in contrast to the closest example disclosed by Tanaka '339, i.e. Example 299, which is comparatively inferior in this regard. Note that Example 299 of Tanaka '339 includes sodium bicarbonate which may account for the preservation of carbon dioxide in its gaseous state, since a carbonate can be used to generate carbon dioxide under appropriate conditions as described in Tanaka '339. In any case Tanaka '339 fails to disclose or suggest the present invention. Further, even assuming that Tanaka '339 supports an allegation of prima facie obviousness, such obviousness has been rebutted by the evidence of unexpected, advantageous properties shown in the Tanaka Declaration discussed above. Therefore, the above rejections based on Tanaka '339 should be withdrawn.

Nishino '189 and Westwood '340 both fail to make up for the above-noted deficiencies of Tanaka '339. Nishino '189 and Westwood '340 are directed to devices which provide a seal for a gas, such as carbon dioxide gas, when it is being exposed to the skin or a limb. However, both of these references fall far short of disclosing, suggesting or providing any basis for one skilled in the art to employ an absorption aid for dissolving carbon dioxide gas, as employed in the device of the present invention. Thus, significant patentable distinctions exist over both of these references, whether taken separately or combined with Tanaka '339. Therefore, the above rejections based on these references in combination with Tanaka '339 should be withdrawn.

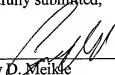
Gedouin '336 additionally fails to make up for the above-noted deficiencies with regard to Tanaka '339 or the other cited references. Note that Gedouin '336 is directed to the use of a depolymerized sodium alginate composition as a cosmetic preparation to protect skin against harmful effects of atmosphere pollution as noted at the top of column 1, for example. Gedouin '336 fails to mention or suggest to one skilled in the art to employ chemical components which react together to form carbon dioxide as required by the examples in Tanaka '339. Gedouin '336 further fails to mention the employment of any type of carbon dioxide gas, such as the gas supplied to skin by the device of Nishino '189. There fails to be any adequate basis for a motivation to one skilled in the art to combine Gedouin '336 with any of the other cited references. Further, Gedouin '336 clearly fails to recognize the advantageous achieved by the present invention as described above. Thus, the rejection based on Gedouin '336 must be withdrawn.

If any questions arise in the above matters, please contact Applicant's representative, Andrew D. Meikle (Reg. No. 32,868), in the Washington Metropolitan Area at the phone number listed below.

If necessary, the Director is hereby authorized in this, concurrent, and future replies to charge any fees required during the pendency of the above-identified application or credit any overpayment to Deposit Account No. 02-2448.

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Respectfully submitted,

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